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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Jenson, M.

Examiner: S. J. Gherbi

Application No.: 10/664,454

Group Art Unit: 3738

Filed: September 17, 2003

Docket: 760-68

For: COVERED STENT WITH BIOLOGICALLY ACTIVE MATERIAL

Dated: May 16, 2005

Confirmation No. 4333

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450. Alexandria, VA 22313-1450.

Date: May 16, 2005

Signature: Barbara Thomas/

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

The Examiner has required restriction under 35 U.S.C. §121 between one of the following groups, which the Examiner has alleged as being distinct inventions:

Group I — Claims 1-27 are drawn to "A Drug Stent-Graft", classified in class 623, subclass 1.41.

Group II — Claims 28-41 are drawn to Methods of Making, classified in class 623, subclass 901.

Group III — Claims 42-47 are drawn to Methods of Use, classified in class 623, subclass 903.

Additionally, the Examiner alleges that the application contains claims directed to the following patentably distinct species of the claimed invention, and requires applicant to elect a single disclosed species for examination:

A. Figures 1-4 and 6;

B. Figure 5; and

C. Figure 7.

Applicant provisionally elects to prosecute Group I, claims 1-27, with traverse. Further, applicant provisionally elects to prosecute species A, Figures 1-4 and 6, with traverse. Applicant's reasons for traversing the restriction requirement are set forth below.

The Examiner indicates that Groups I and II are distinct in that the product as claimed can be made by another and materially different process such as pre-filling reservoirs with a solid degradable bioactive agent and laminating the ends of the tubular stent and liners together. However, a complete search directed to the composite device of the Group I claims would clearly overlap with a search directed to the Group II claims. Therefore, it would appear that an undue burden of search would not be present, and that a co-extensive search would be virtually mandated.

The Examiner also alleges that Groups I and III are distinct because, in the instant case, the product as claimed can be used in a materially different process of using that product, such as "affixing" a device that will not stay in position, but rather degrade over time. Applicant notes that the claimed device may, for example, be a stent-graft or graft, which is suitable for an endoluminal prosthesis for vascular applications. Once inserted into a body lumen, such as a blood vessel, the composite device is affixed. However, contrary to the Examiner's statements, affixing the device to the lumen such that it will stay where positioned does not preclude

degradation over time. For example, at paragraph [0026] in the present application, applicant discloses that the intermediate structural member can be dissolvable or biodegradable. Also, at paragraph [0060], it is disclosed that the stent segments and the polymers forming the polymeric liners of the composite device can be formed from a biostable or bioabsorbable polymer, where the bioactive agent may be delivered to a site where it is needed in part by the process of degradation and resorption of the polymer itself. Therefore, the example provided by the Examiner is not an alternative use, since it is encompassed by the Group III claims. Furthermore, a complete search directed to the device of the Group I claims would extensively overlap the search directed to the method of Group III. Given this overlap, it would therefore appear that no undue burden of search would be placed on the Examiner, in that a co-extensive search would be virtually mandated.

With respect to the Examiner's requirement to elect a single disclosed species, it is noted that the species are related under applicant's disclosure. For example, at paragraph [0082], it is disclosed that the composite device can be a stent-graft, a vascular graft with inclusions or reinforcing fibers, a covered bioresorbable stent, or other similar tubular device formed of multiple layers to create pockets adjacent to at least one of the solid segments of the intermediate structure member interposed between the layers. Thus, regardless of whether the solid segments are solid stent segments or foreign bodies, such as fibers or inclusions, the solid segments serve to produce pockets for containing a bioactive agent in the completed structure. Also, regardless of whether the bioactive agent is encapsulated or free, it is located within the formed pockets for delivery of the bioactive agent to the site of implantation of the device. In view of these commonalities, applicant does not believe that the restriction to a particular species is appropriate.

For these reasons, applicant respectfully requests the requirement for restriction be withdrawn and consideration of all the claims on the merits be commenced. At the very least, applicant requests that Groups I and III be considered together. If the Examiner has any questions with respect to this matter, the Examiner is encouraged to contact the undersigned agent at the telephone number set forth below.

Respectfully submitted,

Gloria K. Szakiel
Registration No. 45,149
Agent for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700